

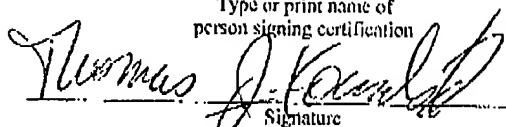
PATENT
830010-2002.2IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Pasternak et al.
 Serial No. : 09/975,812
 For : TOPICAL ANESTHETIC/OPIOID
 FORMULATIONS AND USES THEREOF
 Filed : October 11, 2001
 Examiner : M. Bahar
 Art Unit : 1617

745 Fifth Avenue
New York, NY 10151FACSIMILE

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November 3, 2003_____
Date of SignatureDECLARATION OF GAVRIL PASTERNAK UNDER 37 C.F.R. §1.132

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 Commissioner for Patents
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Dear Sir:

I, Gavril Pasternak, hereby declare as follows:

1. I am a citizen of the United States of America and a named inventor in the above-identified application. I respectfully submit that I am qualified to speak and render opinions as to the disclosure in the present application and the state of the art, as I am considered an expert in the field and have familiarity with the present application and its prosecution. I either

PATENT
830010-2002,2

performed, supervised or controlled any experimental work reported in the present application, in the ordinary course of business.

2. In accordance with the experimental protocol carried out in Example 2, the individual dosage forms of morphine and lidocaine administered topically to subjects in combination were:

	Morphine Dosage	Lidocaine Dosage
Set #1	1.5 mM morphine	0.22 mM lidocaine
	1.5 mM morphine	0.45 mM lidocaine
	1.5 mM morphine	0.9 mM lidocaine
	1.5 mM morphine	1.8 mM lidocaine
Set #2	3.0 mM morphine	0.45 mM lidocaine
	3.0 mM morphine	0.9 mM lidocaine
	3.0 mM morphine	1.8 mM lidocaine
Set #3	4.5 mM morphine	0.22 mM lidocaine
	4.5 mM morphine	0.45 mM lidocaine
	4.5 mM morphine	0.9 mM lidocaine
Set #4	0.4 mM morphine	0.45 mM lidocaine
	0.75 mM morphine	0.45 mM lidocaine
	1.5 mM morphine	0.45 mM lidocaine
	3.0 mM morphine	0.45 mM lidocaine
	6.0 mM morphine	0.45 mM lidocaine
Set #5	0.75 mM morphine	0.9 mM lidocaine
	1.5 mM morphine	0.9 mM lidocaine
	3.0 mM morphine	0.9 mM lidocaine
	4.5 mM morphine	0.9 mM lidocaine
Set #6	0.75 mM morphine	1.8 mM lidocaine
	1.5 mM morphine	1.8 mM lidocaine
	3.0 mM morphine	1.8 mM lidocaine
	4.5 mM morphine	1.8 mM lidocaine

3. Each set was used to calculate the ED₅₀ of either morphine or lidocaine at the specified fixed dose of the other.

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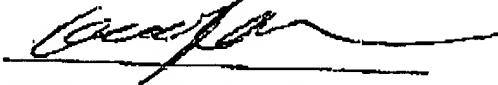
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4. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

11/03/03

Date


Gavril Pasternak, M.D., Ph.D.

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